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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte WILLIAM J. BOYLE, ANDY E. DENISON, BENJAMIN C. HUTER, SCOTT J. HUTER, JOHN E. PAPP, CHARLES R. PETERSON, and KENT C. B. STALKER

Appeal 2009-000173
Application 09/897,295
Technology Center 3700

Decided:¹ July 13, 2009

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and STEPHEN WALSH, *Administrative Patent Judges*.

WALSH, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a medical device. The Patent Examiner rejected the claims for including new matter

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

and for obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

The Specification describes “delivery and recovery sheaths for use with . . . medical devices which deliver self-expanding components . . . for implantation in a patient’s vasculature.” (Spec. 5:2-5.) Claims 3-13, 20-26 and 41-51 are on appeal.² Independent claims 3 and 41 are representative and read as follows:

3. A restraining device for maintaining a self-expanding medical device on a delivery device, comprising:

a restraining sheath having an expandable housing portion adapted to receive and maintain the self-expanding medical device in a collapsed condition on the delivery device, the expandable housing portion being adapted to move between a contracted position and expanded position, the housing portion having sufficient column strength to maintain the self-expanding medical device in its collapsed condition on its delivery device, wherein:

the expandable housing portion is made primarily from an elastic material which is movable between the contracted position and expanded position and includes at least one reinforcing member associated therewith which provides additional column strength to the housing portion but does not interfere with the expansion or contraction of the housing portion.

² Claims 14-19 and 27-32 are also pending but were withdrawn from consideration by the Examiner. (App. Br. 3.) Claims 1, 2 and 33-40 were cancelled. (*Id.*)

41. A restraining device for maintaining a self-expanding medical device on a delivery device, comprising:

a restraining sheath having an expandable housing portion adapted to move between a contracted position and expanded position, and to maintain the self-expanding medical device in a collapsed condition on the delivery device, and a reinforcing member associated with the expandable housing portion to cooperatively provide sufficient strength to the expandable housing portion to the expandable housing portion to maintain the self expanding medical device in its collapsed condition on the delivery device without the reinforcing member interfering with the ability of the expandable housing portion to move between the contracted and expanded positions.

The Examiner rejected the claims as follows:

- claims 3-13, 20-26 and 41-51 under 35 U.S.C. § 112, first paragraph, for claiming new matter; and
- claims 3-13, 20-26 and 41-51 under 35 U.S.C. § 103(a) as obvious over the combined teachings of Hopkins,³ Amplatz⁴ and Kelley.⁵

NEW MATTER

The Examiner contends that the claims contain a limitation directed to a “non-woven” reinforcing member which was not described in the original disclosure. (Ans. 3.) We reverse this rejection because the claims do not contain a limitation directed to a “non-woven” reinforcing member.

Appellants deleted the “non-woven” limitation by amendment filed

³ U.S. Patent No. 6,544,279 B1, issued to L. N. Hopkins et al., Apr. 8, 2003.

⁴ U.S. Patent No. 6,123,715, issued to Curtis Amplatz, Sep. 26, 2000.

⁵ U.S. Patent No. 6,517,765, issued to Gregory Kelley, Feb. 11, 2003.

Nov. 13, 2006. In an Advisory Action mailed Jan. 4, 2007, the Examiner indicated that Appellants' amendment of Nov. 13, 2006, overcame the rejection under § 112, first paragraph. (Evid. Apdx., Exhibit 19, item 5.)

OBVIOUSNESS

The Issue

The Examiner's position is that the Hopkins patent described a restraining device having all but one feature of Appellants' restraining device. (Ans. 4.) "The difference between Hopkins and claim 3 is a reinforcing member associated therewith which provides additional column strength to the housing portion but does not interfere with the expansion or contraction of the housing portion." (*Id.* at 5.) Amplatz and Kelley taught braids reinforcing the wall of a guiding catheter or of tubing, respectively.

(*Id.*) The Examiner concluded it would have been obvious to reinforce Hopkins' expandable housing portion with the braids taught by Amplatz, and to apply Kelley's modify the braids to adjust the flexibility of the tubing.

(*Id.*) "Based upon the teach[ing] of Amplatz of a catheter and the braids used for providing reinforcing means to the wall which can be adjusted as desired and Hopkins is a catheter device one of ordinary skill would look to Amplatz for the teaching of reinforcing means for the wall which can be adjusted to meet specific needs of specific applications." (*Id.* at 10.)

Appellants contend that "the Hopkins device already possesses sufficient column strength," and Hopkins "fails to disclose the use or need for any reinforcing member." (App. Br. 9.) Appellants further contend that the distal end of Hopkins' retrieval sheath "does not move between a

contracted position and an expanded condition as recited in claims 3 and 41.

... [S]ince it appears [in Fig. 23B] that the distal end region 594 has been plastically deformed into the expanded position." (*Id.* at 10.)

According to Appellants, Amplatz concerned guiding catheters, which "do[] not require the ability to expand or collapse, since the tubular structure of the guiding catheter is not designed to expand or collapse radially. . . .

Simply put, the use of a woven braid with an expandable housing would inhibit radial contraction and expansion of the housing." (*Id.* at 11.)

Appellants argue that "while one can increase or decrease the lateral flexibility of the tubing by varying the pitch or braid count, as taught by the Amplatz and Kelley patents, the woven braid or fabric will still inhibit expansion and collapse of the tubing." (*Id.* at 12.) "Thus, the suggested combination of these patents would not create the structure recited in the pending claims." (*Id.*)

The issues with respect to this rejection are

whether the distal end of Hopkins' retrieval sheath moved between contracted and expanded conditions;

whether Amplatz's woven braid would have inhibited radial contraction and expansion; and

whether a person of ordinary skill in the art would have recognized a benefit to reinforcing the Hopkins retrieval sheath to provide additional column strength.

Findings of Fact

Hopkins

1. Hopkins patent is entitled “Vascular Device For Emboli, Thrombus And Foreign Body Removal And Methods Of Use.”
2. Hopkins described a retrieval sheath 592 having an expandable end region 594. (Col. 23, ll. 7-11.)
3. Hopkins’ expandable end region 594 had a deployed state, where the wall flared out, and a contracted state, where the wall was substantially cylindrical. (Col. 23, ll. 11-14.)
4. Hopkins’ end region 594 comprised “a suitable elastomeric material, such as latex, rubber or a synthetic variant thereof.” (Col. 23, ll. 33-34.)
5. Hopkins’ retrieval sheath could be used to retrieve a self expanding medical device, e.g., a collapsed embolic filter. (Col. 23, ll. 19-24.)
6. We find that Hopkins’ sheath had sufficient column strength to maintain the self expanding medical device in a collapsed condition on the delivery device.

Amplatz

7. Amplatz disclosed tubular braids for reinforcing such devices as guiding catheters. (Col. 3, ll. 45-48.)

Kelley

8. Kelley taught reinforced and flexible tubing for devices such as guiding catheters with preferred torque, flexibility and pushable characteristics. (Col. 1, ll. 17-21.)

Principles of Law Relating to Obviousness

Obviousness is a question of law based on fact findings. The scope and content of the prior art are determined; differences between the prior art and the claims at issue are ascertained; the level of skill in the art is resolved; and objective record evidence of nonobviousness is considered. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). A rejection for obviousness must include “articulated reasoning with some rational underpinning to support the legal conclusion.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007), quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

The proper question to ask is whether a person of ordinary skill in the art, facing the wide range of needs created by developments in the field of endeavor, would have seen a benefit to combining the prior art teachings. *KSR*, 550 U.S. at 424; *see also In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004) (the desirability of the combination may arise from nature of the problem, teachings of references, or the ordinary knowledge of those skilled in the art).

Analysis

First, we agree with the Examiner that the distal end of Hopkins’ retrieval sheath moved between a contracted and an expanded condition. The Hopkins sheath was fabricated from elastomeric material such as latex (FF4), and movement between both states is a property of elastomeric materials. We conclude, however, that the Examiner has not established a *prima facie* case of obviousness for adding a “reinforcing member” to the Hopkins sheath.

Claim 3 requires that the “reinforcing member . . . does not interfere with the expansion or contraction of the housing portion.” Claim 41 similarly requires that the reinforcing member be present “without . . . interfering with the ability of the expandable housing portion to move between the contracted and expanded portions.” The Amplatz and Kelley patents did not address delivery devices having housing portions that must move between expanded and contracted states. Instead, Amplatz and Kelley concerned devices such as guiding catheters. (FF7, FF8.) Appellants argue that those devices flex laterally, but they do not expand or contract. (App. Br. 11.) The Examiner does not dispute that argument.

While the Amplatz and Kelley techniques were used to improve such things as guiding catheters, Appellants correctly point out that the Hopkins sheath is not the same kind of catheter. In the retrieval device claimed, the sheath expands and contracts without interference from a reinforcing member. Appellants argue that if the Hopkins sheath were made with the Amplatz and Kelley braid reinforcement, the braid reinforcement would likely impede radial expansion and contraction. (App. Br. 11-12.) The Examiner did not counter that argument and we accept it as factually correct.

The general rule is that “if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.” *KSR*, 550 U.S. at 401. Using the Amplatz and Kelley braid reinforcement in the Hopkins retrieval sheath might have reinforced the Hopkins sheath in the same way that Amplatz’ guiding catheter was reinforced. However, the reinforcement

would not have produced the claimed invention, in which the reinforcing member does not interfere with expansion and contraction. We conclude that a person of ordinary skill in the art would not have recognized a benefit to reinforcing the Hopkins retrieval sheath to provide additional column support, and that a *prima facie* case of obviousness was not established.

CONCLUSIONS OF LAW

The distal end of Hopkins' retrieval sheath moved between contracted and expanded conditions;

Amplatz's woven braid would have inhibited radial contraction and expansion if used in Hopkins' sheath; and

a person of ordinary skill in the art would not have recognized a benefit to reinforcing the Hopkins retrieval sheath to provide additional column strength.

SUMMARY

We reverse the rejection of claims 3-13, 20-26 and 41-51 under 35 U.S.C. § 112, first paragraph, for claiming new matter; and

we reverse the rejection of claims 3-13, 20-26 and 41-51 under 35 U.S.C. § 103(a) as obvious over the combined teachings of Hopkins, Amplatz and Kelley.

REVERSED

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dm

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